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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,770	01/29/2004	Richard A. Gambale	B0410/7280D1	7050

22832 7590 08/01/2006

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EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,770	GAMBALE ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 33-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 33-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/7/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment and request for reconsideration filed 05/24/2006.

The rejection under 35 USC 102(b) over Altman is hereby withdrawn.

The following rejection is maintained:

Claim Rejections - 35 USC § 112

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12 and 13 are rejected because the specification does not describe "withdrawing the delivery system from its proximity to the muscle".

Response to Arguments

Applicant's arguments filed 05/24/2006 have been fully considered but they are not persuasive.

Applicant argues that support for the phrase in question "can be found at page 21, line 16 to page 4, and on page 6, lines 23-24, and is shown in Figs. 7a-7d. However, upon review of those sections no support could be found. Additionally, the citation is confusing in its reference to "page 21, line 16 to page 4". Clarification is requested as well as the specific areas where support for this language can be found. The rejection under 35 USC 112, first paragraph for lack of written description is therefore maintained.

The following new rejections are made in view of applicant's amendment of the claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 33-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 11 contain the phrase "comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities". This limitation has no support in the original specification in that page 10, lines 15-24; and page 11, lines 22-23 the drug can be contained in an internal reservoir or within the lumen of a spring. There is no support for external projections other than bellows described at page 11, lines 19-23.

Claim 33 sets out new matter in that the "at least one opening in the body open to the lumen" has no support in the original specification. Instead, the specification seems to indicate that the opening occurs in the bellows, not the body of the implant (see page 11, lines 21-23).

Claim 34 sets out new mater in the phrase "retained by a surface of the body". The specification at page 10, lines 1-3 indicates it is affixed to the surface.

Claim 35 sets out new matter in that there is no support for having the drug releasing compound in the lumen of the body. Page 10, line 21 indicates that it may be in the lumen of the spring.

Claim 37 is has no support in the original specification in that the language of page 10, lines 1-3 indicates that it may be affixed to one of its surfaces.

Claim 38 has no support in the original specification in that the specification indicates incorporation of the radiation source into the material employed to form the implantable device.

Claim 39 lacks support in the original specification in that muscle relaxation is limited to myocardium. Further, "annular ripples" could not be found anywhere in the specification.

Claim 40 contains new matter in reference to the "external projections ..defined by the tighter pitch spring sections". The specification refers to "inner tighter pitch spring sections" at page 20, line 12.

Claim 42 contains new matter in that the "at least one opening" open again appears to be in the bellows, and the drug is found either in a reservoir or lumen of the spring (see above citations).

This is considered a rejection of new matter in the claims. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 33-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,692,520 (US'520). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'520 set out an apparatus for promoting angiogenesis comprising a flexible body formed of a biocompatible material and being dimensionally adapted for implantation within the tissue of a muscle wherein said flexible body comprises a bellows for expanding and contracting responsive to muscle relaxation and contraction wherein said body defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling and external projections configured to create cavities between tissue and the body to thereby stimulate angiogenesis (claim 1). The projections are defined by annular ripples of the

bellows (claim 2). At least one port in the body open to the lumen (claim 3). A drug releasing compound is retained by a surface of the device (claim 4) or may be contained within the lumen of the body (claim 5). The drug may also be found in a coating of the device (claim 6). At least a portion of the device is formed from a drug releasing compound (claim 7). The drug releasing compound diffuses through the port during compression of the bellows (claim 8). The apparatus may additionally comprise a radiation source (claim 9). Those of ordinary skill would have expected similar therapeutic results from the instant method given the claims of US'520 given that the same apparatus is used for the same purpose of stimulating angiogenesis. As such, the instant claims would have been obvious to those of ordinary skill at the time of invention given the claims of US'520.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carlos A. Azpuru
Primary Examiner
Art Unit 1615